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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

UNITED STATES OF AMERICA, Plaintiff, v. VALLEY PROCESSING, INC., a corporation, and MARY ANN BLIESNER, individually, Defendants.	Case No. 1:20-cv-3191 **COMPLAINT FOR PERMANENT INJUNCTION**

Plaintiff United States of America, by and through its undersigned attorneys,

respectfully represents as follows:

INTRODUCTION

1. The United States of America brings this action on behalf of the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin and restrain Valley Processing, Inc. ("Valley Processing") and Mary Ann Bliesner (collectively, "Defendants"), from introducing or delivering for introduction into interstate commerce, or the causing thereof, food that is adulterated, in violation of 21 U.S.C. § 331(a), and causing such food to become adulterated while it is held for sale after shipment of one or more of its components in interstate commerce, in violation of 21 U.S.C. § 33l(k).

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

3. Venue in this district is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Valley Processing is a Washington corporation previously headquartered at 108 Blaine Ave., Sunnyside, Washington 98944. Valley Processing manufactured single strength fruit juice and fruit juice concentrate, including bulk apple, pear, and grape juice products distributed in pails, barrels, totes, and tanker trucks. The company was incorporated on July 16, 1980, and had seventy-one (71) employees. The company supplied apple juice through one customer to the United States Department of

Agriculture ("USDA") school lunch program, providing approximately 2,964,000 apple juice servings to schoolchildren every year. The company's facilities included three manufacturing plants, an ambient warehouse ("Mojo Warehouse"), a cold room, and three coolers, all located at the Blaine Avenue location. In addition to the Blaine Avenue facilities, Defendants also stored product in an ambient storage facility, where product was stored outside, located at 130 US Grape Road, Sunnyside, Washington 98944, and in another storage room known as the Briner Cold Room, located in the maintenance building at 105 South First Street, Sunnyside, Washington, 98944.

5. Defendant Mary Ann Bliesner is Valley Processing's Owner, President, Secretary, and Treasurer. At all times relevant to the allegations in this Complaint, Ms. Bliesner was responsible for the day-to-day management of the company's juice production facility, including supervising and training employees. She was the most responsible person at the company, overseeing operations, and had the authority to take corrective actions, as well as the authority to hire and fire employees.

HEALTH RISKS ASSOCIATED WITH DEFENDANTS' PRODUCTS

6. Defendants' juice products have been found to contain inorganic arsenic and patulin, both toxins which pose a health risk to consumers.

7. Arsenic is an element that occurs in the environment from both natural and manmade sources, including the erosion of arsenic-containing rocks, volcanic eruptions, contamination from mining and smelting ores, and previous or current use of arsenic-containing pesticides. Arsenic is found in both inorganic and organic forms, and

inorganic arsenic is generally considered more toxic than organic arsenic. Exposure to inorganic arsenic has been associated with cancer, skin lesions, cardiovascular disease, neurotoxicity and diabetes in humans. Inorganic arsenic is a hazard that is reasonably likely to occur in processing both apple and pear juice products. Thermal processing, including pasteurization, does not destroy arsenic.

8. Patulin is a mycotoxin produced by certain species of molds that may grow on a variety of foods, including apples and pears. High levels of patulin can be produced in rotting or moldy apples or pears. Apples and pears that have been damaged, by falling off the tree, by insects or birds, or by rough handling, are more susceptible to the growth of patulin producing molds. Storage of apples under conditions that do not control mold growth can also lead to high levels of patulin. If fallen fruit, moldy, rotten, bruised, damaged, or improperly stored apples are used to make juice, high levels of patulin can occur in the juice even if it is pasteurized. Thermal processing, including pasteurization, does not destroy patulin.

9. Exposure to high levels of patulin over time may pose health hazards in humans, including nausea, vomiting, and gastrointestinal disturbances. FDA has established an action level of 50 parts per billion ("ppb") in apple juice. Patulin can be destroyed by fermentation, so it is not found in either alcoholic beverages or vinegars produced from apple or pear juices.

REGULATORY FRAMEWORK

10. Defendants' juice products are food within the meaning of the Act, 21 U.S.C. §321(1).

11. FDA's food current good manufacturing practice ("CGMP") regulations establish basic practices that must be followed, and conditions that must be maintained, by entities or individuals, like Defendants, who receive, prepare, process, pack, hold, or distribute food. *See* 21 C.F.R. Part 117 subpart B. The purpose of CGMP is to ensure that food is processed in a safe and sanitary manner.

12. Juice processors must monitor, with sufficient frequency, their sanitation conditions and practices used during processing to ensure, at a minimum, that they conform with CGMP regulations for manufacturing, packing, or holding human food, *see, e.g.*, 21 C.F.R. Part 117 subpart B. 21 C.F.R. § l 20.6(b). Violations of CGMP help to determine whether the facilities, methods, practices, and controls used to process juices are sanitary and safe. 21 C.F.R. § 120.5; *see also* 21 C.F.R. Part 117 subpart B.

13. Defendants are also subject to the juice Hazard Analysis and Critical Control Point ("HACCP") regulation, 21 C.F.R. Part 120, because they manufacture juice products that are both sold as juice and that are "used as an ingredient in beverages," *see* 21 C.F.R. § 120.1, and because Defendants' manufacturing operations constitute "processing," as defined by 21 C.F.R. § 120.3(i)(l).

14. The juice HACCP regulation, 21 C.F.R. Part 120, creates a system to prevent the occurrence of potential food hazards in juice. HACCP achieves this goal by requiring

juice processors to assess their processing operations (known as the hazard analysis), identify points in the process at which various hazards may occur (known as critical control points), and establish measures to control, prevent, or eliminate those hazards (known as critical limits). *See* 21 C.F.R. §§ 120.7-120.13.

15. Under the juice HACCP regulation, every juice processor must develop, or have developed for it, a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur during processing for each type of juice produced and to identify control measures that the processor can apply to control those hazards. 21 C.F.R. § 120.7(a). Whenever a hazard analysis identifies one or more food hazards that are reasonably likely to occur during processing, the processor must have and implement a written HACCP plan to control the identified food hazards. 21 C.F.R. § 120.8.

16. Additionally, a juice processor's HACCP plan must identify "critical control points" ("CCPs") in the juice manufacturing process at which a control measure can be applied that "is essential to reduce an identified food hazard to an acceptable limit." 21 C.F.R. §§ 120.3(d), 120.7(a)(5).

17. For each CCP, the HACCP plan must establish a "critical limit," *i.e.*, the "maximum or minimum value to which a physical, biological, or chemical parameter must be controlled … to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food hazard." 21 C.F.R. §§ 120.3(e), 120.8(b)(3).

18. The juice HACCP regulation further requires that juice processors have and

implement a sanitation standard operating procedure that addresses sanitation conditions and practices before, during, and after processing. 21 C.F.R. § 120.6.

19. Under the Act, 21 U.S.C. § 342(a)(4), food is adulterated if it has been "prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

20. Under the Act, 21 U.S.C. § 342(a)(3), food is adulterated if "it consists in whole or in part of any filthy, putrid, decomposed substance, or if it is otherwise unfit for food."

21. Juice products that are processed without adhering to the CGMP requirements or the juice HACCP regulation are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

22. In addition, juice products are adulterated under 21 U.S.C. § 342(a)(4) when a manufacturer's quality control operations do not ensure food is suitable for human consumption. *See* 21 C.F.R. § 117.1(a)(1)(ii); 21 C.F.R. § 117.80(a)(2).

DEFENDANTS' VIOLATIONS

23. Defendants violated 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, or the causing thereof, food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4) and 21 U.S.C. § 342(a)(3).

24. Defendants violated 21 U.S.C. § 331(k) because they cause food held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) and 21 U.S.C. § 342(a)(3).

25. Defendants distributed their juice products in interstate commerce to customers located in California.

26. Defendants received tartaric acid, a preservative used in their juice products, from a supplier in Spain.

27. Defendants' juice products are adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth, or whereby they may have been rendered injurious to health. In addition, because Defendants' juice products are processed without adhering to the requirements of 21 C.F.R. Part 120, they are adulterated within the meaning of 21 U.S.C. § 342(a)(4). *See* 21 C.F.R. § 120.9. Defendants' failure to have and implement an adequate HACCP plan created insanitary conditions that may render their juice injurious to health. *See* 21 C.F.R. § 120.9.

28. In addition, Defendants' juice products "consist[] in whole or in part of any filthy, putrid, or decomposed substance" or are "otherwise unfit for food," and thus are adulterated under 21 US.C. § 342(a)(3).

FDA INSPECTIONS

29. Defendants have an extensive history of processing juice under grossly insanitary conditions and with an inadequate HACCP plan that has not been properly or fully implemented. This pattern of continuing violative conduct has been documented by FDA investigators during inspections on May 6 to June 20, 2019 (the "June 2019 inspection"); April 30 to July 31, 2018 (the "July 2018 inspection"); March 28 to April

26, 2017 (the "April 2017 inspection"); and December 7, 2015, to January 29, 2016 (the "January 2016 inspection").

30. Although FDA found violations of CGMP and HACCP during all inspections, as discussed further below, during the July 2018 inspection, FDA investigators learned that Defendants were storing grape juice concentrate outside in covered barrels at ambient temperatures at a previously undisclosed facility on US Grape Road. Many of these barrels contained grape juice concentrate that was several years old, with some lot codes dating back to 2008. As confirmed by FDA sampling, the grape juice concentrate in these barrels was contaminated by filth and mold, and thus not suitable for human consumption.

31. FDA investigators also discovered that Defendants processed the "bottoms" of stored grape juice concentrate. The "bottom" of juice concentrate is the leftover sludge that accumulates at the bottom of the barrel, after Defendants open a barrel to pull product off the top, exposing all of the product in the barrel to possible contamination. Defendants diluted the "bottoms," likely to contain contaminants, to be blended with newer juice. Defendants mixed the juice concentrate from the both the ambient barrels and the "bottoms" with newer lots to hide the contamination. Defendants promised to stop both of these practices, described in paragraphs 30 and 31, but as detailed below, FDA investigators confirmed during the June 2019 inspection that Defendants continued both of them.

Most Recent Inspection

32. During the June 2019 inspection, FDA investigators observed multiple violations of the CGMP requirements, as the Defendants continued their grossly insanitary manufacturing and storage practices for their juice products, and recurring HACCP violations.

CGMP Violations

33. Defendants failed to comply with 21 C.F.R. § 120.6(b), which requires them to monitor sanitation conditions and practices with sufficient frequency during juice processing to ensure conformance with CGMP, as set forth in 21 C.F.R. Part 110 and 21 C.F.R. Part 117, subpart B. FDA investigators observed numerous deviations from CGMP including, but not limited to, the following:

a. Defendants did not have appropriate quality control operations to ensure that food is fit for human consumption, as required by 21 C.F.R. § 117.80(a)(2). During the June 2019 inspection, FDA investigators observed that, despite Defendants' promises to stop the practice both during and following the July 2018 inspection, Defendants continued to blend grape juice concentrate with lot numbers dating back to 2011, and stored outside at ambient temperatures, with newer product. FDA investigators also observed that quality processes that Defendants developed and implemented to ensure that all blended products were fit for human consumption were inadequate as written and were often not followed;

b. Defendants did not conduct their operations under conditions and controls

necessary to minimize the potential for contamination of food, as required by 21 C.F.R. § 117.80(c). Specifically, during the 2019 inspection, FDA investigators observed Defendants continuing to blend "bottoms," likely to contain contaminants, with newer juice. Defendants still used this process despite being told at the July 2018 inspection by FDA that this process could make the blended juice unfit for human consumption and promising to FDA investigators that they would discontinue this practice;

c. Defendants did not maintain their facility in a clean and sanitary condition or keep the facility in good repair, as required by 21 C.F.R. § 117.35(a). For example, FDA investigators observed gaps in the walls of the Briner Cold Room and the Mojo Warehouse leading directly outside and liquid leaking from a hole in the roof at the Mojo Warehouse onto cleaning materials;

d. Defendants failed to exclude pests from their facility to protect against contamination of food, as required by 21 C.F.R. § 117.35(c). For example, FDA investigators observed a dead squirrel on the floor of, and live birds flying in, the Mojo Warehouse, and bird feathers, bird excreta, and insect fragments on barrels holding juice concentrate in the Briner Cold Room; and

e. Defendants failed to develop any sanitation standard operating procedures ("SSOPs"), or monitor sanitation with sufficient frequency, in several locations at their facility, as required by 21 C.F.R. § 120.6(b). Specifically, FDA investigators observed that Defendants did not have any SSOPs or sanitation monitoring records for the Briner Cold Room or US Grape Road. Defendants had a sanitation monitoring record for the

Mojo Warehouse that recorded conditions on a weekly basis, but the record from five days before the inspection showed no insanitary conditions, while FDA investigators observed egregious insanitary conditions, including a dead squirrel, live birds, bird and mouse excreta at that location. Defendants did not have an SSOP for the Mojo Warehouse.

HACCP Violations

34. During the June 2019 inspection, FDA investigators observed that Defendants had not adequately corrected the HACCP violations that FDA previously noted related to the control of inorganic arsenic in apple and pear juice products, and patulin in apple and pear juice products. These HACCP violations were the same or similar to previous inspections, including, but not limited to:

a. Defendants failed to adequately implement the monitoring procedures at critical control points that they identified in their HACCP plans, in violation of 21 C.F.R. § 120.8. For example:

(i) Defendants' HACCP plan to control inorganic arsenic required Defendants to sample apple juice products for total arsenic levels, and to perform additional testing to determine inorganic arsenic levels if total arsenic levels are above 10 ppb and less than 12 ppb. FDA investigators observed that one lot of apple juice contained 28 ppb total arsenic, but Defendants did not test the inorganic arsenic levels or divert the lot from distribution;

(ii) Defendants also failed to monitor the critical limits for patulin in

their apple and pear juice products. Defendants' HACCP plan included the critical limit to control patulin: "No visible rotten, moldy or deteriorating apples or pears." But during a ten-minute period at the June 2019 inspection, FDA investigators observed approximately 46 apples that were visibly deteriorated with mold and rot pass through the sorting/culling critical control point;

b. Defendants failed to adequately implement corrective actions identified in their HACCP plans, in violation of 21 C.F.R. § 120.l0(a). For example:

(i) Defendants' HACCP plans to control inorganic arsenic for both apple and pear juice products included the following corrective actions for the detection of high levels of inorganic arsenic: "high levels will be investigated, analyzed, and trended to ascertain potential origin of high arsenic" and "supplier may be removed from supplier list if found to be source of contamination." During the June 2019 inspection, FDA investigators found that 17 lots of apple juice products produced between July 31, 2018, the date of the close of the previous FDA inspection, and April 10, 2019, had total arsenic levels that exceeded 12 ppb, and 2 lots of pear juice products produced between the same dates had total arsenic levels that exceeded 23 ppb. Defendants only collected the total arsenic data but did not investigate, analyze, or trend the data to determine the cause of the high arsenic in the juice products;

(ii) Defendants' HACCP plan to control patulin also required that they investigate, track, or trend any patulin levels above the critical limit of 50 ppb to determine the cause. FDA investigators found no evidence that Defendants investigated,

tracked, or trended any patulin levels above the critical limit of 50 ppb; and

c. Defendants failed to identify an appropriate critical limit for controlling a known hazard, as required by 21 C.F.R. § 120.8(a)(3). For example, FDA investigators found that in October 2018, Defendants changed their HACCP plan for control of patulin, raising the critical limit for core rot at the sort/cull critical control point from less than 1% to less than 10%, meaning that whereas they had previously accepted for processing any apple consisting of 1% or less of core rot they now process any apple consisting of 10% or less of core rot. Defendants made this change in their written HACCP plan despite a history of high patulin levels and after being advised by FDA that apples with a small percentage of rot can produce juice with high levels of patulin. When questioned by FDA investigators about the change, Defendant Mary Ann Bliesner was unaware of the change, despite signing the revised HACCP plan, and could not provide any scientific justification or support for the change.

Previous Inspections

35. FDA investigators observed significant ongoing violations of the Act, the CGMP requirements, and the juice HACCP regulations during its July 2018, April 2017, and January 2016 inspections, and issued Lists of Inspectional Observations ("Forms FDA-483") at the conclusion of each inspection. The Forms FDA-483 included observations of the same type of deficiencies observed at the June 2019 inspection.

Previous CGMP Violations

36. At all three previous inspections, FDA investigators observed that Defendants failed to comply with 21 C.F.R. § 120.6(b) that required them to monitor sanitation conditions and practices with sufficient frequency during juice processing to ensure conformance with CGMP, as set forth in 21 C.F.R. Part 110 and 21 C.F.R. Part 117, subpart B. FDA investigators observed numerous deviations from CGMP including, but not limited to, the following:

a. Defendants did not have appropriate quality control operations to ensure that food is fit for human consumption, as required by 21 C.F.R. § 117.80(a)(2). For example, during the 2018 inspection, FDA investigators discovered Defendants were storing years old grape juice concentrate outside in covered barrels at ambient temperatures. The grape juice concentrate in these barrels was contaminated by filth and mold, and thus not suitable for human consumption. Defendants mixed the juice concentrate from these barrels with newer lots to hide the contamination;

b. Defendants did not conduct their operations under conditions and controls necessary to minimize the potential for contamination of food, as required by 21 C.F.R. § 117.80(c). FDA investigators also discovered in 2018 that Defendants process the "bottoms" of stored grape juice concentrate. The "bottom" of juice concentrate is the leftover sludge that accumulates at the bottom of the barrel, after Defendants open a barrel to pull product off the top, exposing all of the product in the barrel to possible contamination. Defendants dilute the "bottoms," likely to contain contaminants, to be

blended with newer juice;

c. Defendants failed to exclude pests from their facility to protect against contamination of food, as required by 21 C.F.R. § 117.35(c). During the 2018, 2017, and 2016 inspections, FDA investigators observed numerous live and dead animals, including mice, rats, squirrels, and birds, throughout various buildings used for both storage and manufacturing. In several instances, FDA investigators also observed rodent excreta on top of the barrels used to store juice products; and

d. Defendants failed to monitor sanitation conditions and practices with sufficient frequency during juice processing to ensure conformance with CGMP, as required by 21 C.F.R. § l 20.6(b). For example, during the 2018 inspection, FDA investigators found that Defendants' sanitation records did not reflect any of the insanitary conditions that FDA investigators observed, and Defendants' sanitation program excluded the US Grape Road location and the Mojo Warehouse.

Previous HACCP Violations

37. During all three previous inspections, FDA investigators observed recurring significant HACCP violations related to the control of inorganic arsenic in apple and pear juice products and patulin in apple and pear juice products. These HACCP violations included, but were not limited to:

a. Defendants failed to adequately implement the monitoring procedures at CCPs that they had identified in their HACCP plans, in violation of 21 C.F.R. § 120.8. Specifically, at all three previous inspections, Defendants failed to adequately monitor

core rot, which is necessary to control the development of patulin; and

b. Defendants failed to adequately implement corrective actions identified in their HACCP plans, in violation of 21 C.F.R. § 120.10(a). At all three previous inspections, FDA investigators observed that Defendants failed to implement corrective actions, including performing investigations into deviations from critical limits, identified in their HACCP plans for the hazards of inorganic arsenic and patulin.

PRIOR NOTICE

38. Defendants have received ample notice that their juice processing operations violate the law and that continued violations could lead to regulatory action. At the close of the June 2019, July 2018, April 2017, and January 2016 inspections, FDA investigators issued Forms FDA-483 to Defendants that notified them of the investigators' observations. FDA investigators also discussed their observations with Defendants and encouraged them to make necessary corrections.

39. In addition, following the January 2016 inspection, FDA sent Defendants a Warning Letter dated June 26, 2016, that detailed their CGMP and HACCP violations, and discussed these violations with Defendants at a regulatory meeting at FDA's Seattle District Office on August 21, 2017.

40. In response to the inspections, Warning Letter, and regulatory meeting, the Defendants repeatedly promised, both orally and in numerous letters to FDA, to bring their facility into compliance with regulatory requirements.

41. Specifically, Defendants promised to suspend their violative practices of

holding juice products outside and blending older juice product that had been subject to possible contamination with newer juice products, and to adequately implement their HACCP plans.

42. The most recent FDA inspection showed that Defendants kept none of these promises. Although Defendants claimed to be interested in making necessary changes, compliance with the law has clearly not been a priority.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates), who receive notice of the Court's order, directly or indirectly, from violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or the causing thereof, food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4) and (a)(3), in violation of 21 U.S.C. § 331(a), and causing such food to become adulterated, within the meaning of 21 U.S.C. § 342(a)(4) and (a)(3), while it is held for sale after shipment of one or more of its components in interstate commerce, in violation of 21 U.S.C. § 33l(k).

II. Order Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in

active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates), who receive notice of the Court's order to cease, directly or indirectly, receiving, processing, manufacturing, preparing, packaging, holding, and distributing any article of food within the meaning of 21 U.S.C. § 321(f), at or from Defendants' facility (and any other or new location at or from which Defendants receive, prepare, process, pack, hold, or distribute food) unless and until Defendants bring their operations into compliance with the Act and its implementing regulations to the satisfaction of FDA; and

III. Award the United States its costs herein, including the costs of investigation to date, and such other relief as the Court may deem just and proper.

Dated this 6th day of November, 2020.

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JS 44 (Rev. 10/20)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

THE UNITED STATES OF AMERICA

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

See Attachment A

DEFENDANTS

VALLEY PROCESSING, INC., a corporation, and MARY ANN BLIESNER, individually.

County of Residence of First Listed Defendant Yakima County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

See Attachment A

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- [X] 1 U.S. Government Plaintiff
- [ ] 2 U.S. Government Defendant
- [ ] 3 Federal Question *(U.S. Government Not a Party)*
- [ ] 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	[ ] 1	[ ] 1	Incorporated *or* Principal Place of Business In This State	[ ] 4	[ ] 4
Citizen of Another State	[ ] 2	[ ] 2	Incorporated *and* Principal Place of Business In Another State	[ ] 5	[ ] 5
Citizen or Subject of a Foreign Country	[ ] 3	[ ] 3	Foreign Nation	[ ] 6	[ ] 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
[ ] 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	[ ] 625 Drug Related Seizure of Property 21 USC 881	[ ] 422 Appeal 28 USC 158	[ ] 375 False Claims Act
[ ] 120 Marine	[ ] 310 Airplane	[ ] 365 Personal Injury - Product Liability	[ ] 690 Other	[ ] 423 Withdrawal 28 USC 157	[ ] 376 Qui Tam (31 USC 3729(a))
[ ] 130 Miller Act	[ ] 315 Airplane Product Liability	[ ] 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	[ ] 400 State Reapportionment
[ ] 140 Negotiable Instrument	[ ] 320 Assault, Libel & Slander	[ ] 368 Asbestos Personal Injury Product Liability		[ ] 820 Copyrights	[ ] 410 Antitrust
[ ] 150 Recovery of Overpayment & Enforcement of Judgment	[ ] 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	[ ] 830 Patent	[ ] 430 Banks and Banking
[ ] 151 Medicare Act	[ ] 340 Marine	[ ] 370 Other Fraud	[ ] 710 Fair Labor Standards Act	[ ] 835 Patent - Abbreviated New Drug Application	[ ] 450 Commerce
[ ] 152 Recovery of Defaulted Student Loans (Excludes Veterans)	[ ] 345 Marine Product Liability	[ ] 371 Truth in Lending	[ ] 720 Labor/Management Relations	[ ] 840 Trademark	[ ] 460 Deportation
[ ] 153 Recovery of Overpayment of Veteran's Benefits	[ ] 350 Motor Vehicle	[ ] 380 Other Personal Property Damage	[ ] 740 Railway Labor Act	[ ] 880 Defend Trade Secrets Act of 2016	[ ] 470 Racketeer Influenced and Corrupt Organizations
[ ] 160 Stockholders' Suits	[ ] 355 Motor Vehicle Product Liability	[ ] 385 Property Damage Product Liability	[ ] 751 Family and Medical Leave Act	SOCIAL SECURITY	[ ] 480 Consumer Credit (15 USC 1681 or 1692)
[ ] 190 Other Contract	[ ] 360 Other Personal Injury		[ ] 790 Other Labor Litigation	[ ] 861 HIA (1395ff)	[ ] 485 Telephone Consumer Protection Act
[ ] 195 Contract Product Liability	[ ] 362 Personal Injury - Medical Malpractice		[ ] 791 Employee Retirement Income Security Act	[ ] 862 Black Lung (923)	[ ] 490 Cable/Sat TV
[ ] 196 Franchise				[ ] 863 DIWC/DIWW (405(g))	[ ] 850 Securities/Commodities/ Exchange
				[ ] 864 SSID Title XVI	[X] 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS		[ ] 865 RSI (405(g))	[ ] 891 Agricultural Acts
[ ] 210 Land Condemnation	[ ] 440 Other Civil Rights	Habeas Corpus:	IMMIGRATION		[ ] 893 Environmental Matters
[ ] 220 Foreclosure	[ ] 441 Voting	[ ] 463 Alien Detainee	[ ] 462 Naturalization Application	FEDERAL TAX SUITS	[ ] 895 Freedom of Information Act
[ ] 230 Rent Lease & Ejectment	[ ] 442 Employment	[ ] 510 Motions to Vacate Sentence	[ ] 465 Other Immigration Actions	[ ] 870 Taxes (U.S. Plaintiff or Defendant)	[ ] 896 Arbitration
[ ] 240 Torts to Land	[ ] 443 Housing/ Accommodations	[ ] 530 General		[ ] 871 IRS—Third Party 26 USC 7609	[ ] 899 Administrative Procedure Act/Review or Appeal of Agency Decision
[ ] 245 Tort Product Liability	[ ] 445 Amer. w/Disabilities - Employment	[ ] 535 Death Penalty			[ ] 950 Constitutionality of State Statutes
[ ] 290 All Other Real Property	[ ] 446 Amer. w/Disabilities - Other	Other:			
	[ ] 448 Education	[ ] 540 Mandamus & Other			
		[ ] 550 Civil Rights			
		[ ] 555 Prison Condition			
		[ ] 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

- [X] 1 Original Proceeding
- [ ] 2 Removed from State Court
- [ ] 3 Remanded from Appellate Court
- [ ] 4 Reinstated or Reopened
- [ ] 5 Transferred from Another District *(specify)*
- [ ] 6 Multidistrict Litigation - Transfer
- [ ] 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
21 U.S.C. § 332(a),

Brief description of cause:
Defendants' food is adulterated under 21 U.S.C. § 342(a)(4) and defendants are therefore violating 21 U.S.C. § 331(a),(k).

VII. REQUESTED IN COMPLAINT:

[ ] CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ Permanent Injunction

CHECK YES only if demanded in complaint:

JURY DEMAND: [ ] Yes [X] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 11-6-2020

SIGNATURE OF ATTORNEY OF RECORD Kendrack D. Lewis

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

ATTACHMENT A

ATTORNEYS FOR PLAINTIFF UNITED STATES OF AMERICA:

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Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

UNITED STATES OF AMERICA, Plaintiff, v. VALLEY PROCESSING, INC., a corporation, and MARY ANN BLIESNER, individually, Defendants.	Civil Action No. 1:20-cv-3191 **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Valley Processing, Inc. ("Valley

Processing") and Mary Ann Bliesner, (collectively, "Defendants"), and Defendants having appeared and consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. §§ 301 *et seq*.

3. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or the causing thereof, articles of food within the meaning of 21 U.S.C. § 321(f), namely single strength fruit juice and fruit juice concentrate, including bulk apple, pear, and grape juice products ("juice products") that are adulterated, in violation of 21 U.S.C. § 331(a).

4. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration of articles of food while such articles are held for sale after shipment of one or more components in interstate commerce.

5. The articles of food are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health.

6. The articles of food are also adulterated within the meaning of 21 U.S.C. § 342(a)(3) in that the food "consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food."

7. Defendants represent to the Court that, with the exception of holding and shipping product for destruction pursuant to paragraph 9, at the time of entry of this Decree, they are not engaged in processing, manufacturing, preparing, packing, holding, or distributing any type of food. With the exception of any product in Defendant's possession that is covered by paragraph 9, if Defendants later intend to resume processing, manufacturing, preparing, packing, holding, or distributing food, they must first notify the United States Food and Drug Administration ("FDA") in writing at least ninety (90) calendar days in advance of resuming operations and comply with Paragraph 8 of this Decree. This notice shall identify the type(s) of food Defendants intend to receive, prepare, process, pack, hold, or distribute. Defendants shall not resume operations until FDA has inspected the Defendants' facility(ies) and operations pursuant to Paragraph 8(B)(xiv), Defendants have paid the costs of such inspection(s) pursuant to Paragraph 12, and Defendants have received written notice from FDA, as required by Paragraph 8(B)(xv), and then shall resume operations only to the extent authorized in FDA's written notice.

8. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals,

directors, partnerships, corporations, subsidiaries, and affiliates) who receive notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly receiving, processing, manufacturing, preparing, packing, holding, and/or distributing, at or from any facility from which Defendants receive, prepare, process, manufacture, pack, hold, and/or distribute food ("Defendants' facilities"), any article of food, unless and until the following occur:

A. Defendants select an expert or experts (the "sanitation expert") having no personal or financial ties (other than a consulting agreement) to the Defendants or the Defendants' manufacturing operations and who, by reason of background, education, training, and experience, is qualified to develop, and ensure adequate implementation of, a written sanitation control program, covering the Defendants' manufacturing processes, cleaning and sanitizing operations, pest control, employee health and hygiene precautions, and plant construction and maintenance (including the plant's buildings and sanitation-related systems (plumbing, sewage disposal), equipment, and utensils contained therein), to protect against contamination of food, food-contact surfaces, and food-packaging materials with chemicals, toxins, microorganisms, and filth;

i. Defendants inform FDA in writing of the name and qualifications of the sanitation expert(s) as soon as they retain such expert. The sanitation expert(s) develops a written sanitation control program for preparing, packing, holding, and distributing the Defendants' juice products;

ii. FDA approves, in writing, the sanitation control program developed by the sanitation expert(s);

iii. Defendants make English and Spanish versions of the sanitation control program available and accessible to all their employees;

iv. Defendants develop a written employee training program (in English and Spanish) that includes, at a minimum, instruction in sanitation control requirements for food-handling and manufacturing, and the Defendants document that each employee has received such training;

v. Defendants assign the responsibility and authority for implementing and monitoring the sanitation control program on a continuing basis to an employee who is trained in sanitation control requirements;

vi. The sanitation expert(s) inspects the Defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein to determine whether the Defendants have adequately established and implemented the FDA-approved sanitation control program, whether Defendants have adequately addressed the FDA investigators' inspectional observations listed on each Form FDA-483 issued to the Defendants since 2016, and whether Defendants comply with Current Good Manufacturing Practice ("CGMP") requirements set forth in 21 C.F.R. Part 117 subparts A, B, and F; and

vii. The sanitation expert certifies in writing to FDA that Defendants: (a) have adequately established and implemented the FDA-approved sanitation control

program; (b) have adequately addressed FDA investigators' inspectional observations listed on each Form FDA-483 issued to the Defendants since 2016; and (c) comply with the CGMP requirements in 21 C.F.R. Part 117 subparts A, B, and F.

B. Defendants retain, at Defendants' expense, an independent person or persons ("expert"), who by reason of background, education, training, and experience, is qualified to develop and implement a Hazard Analysis Critical Control Point ("HACCP") plan for juice. The expert shall be without personal or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families.

i. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity of the expert as soon as they retain such expert;

ii. The expert develops written HACCP plans for each type of juice processed by Defendants, consistent with 21 C.F.R. § 120.8(a)-(c);

iii. FDA has approved, in writing, the HACCP plan developed by the expert;

iv. Defendants establish and implement to FDA's satisfaction the written HACCP plan, developed by the expert and approved in writing by FDA, that is adequate to control food safety hazards likely to occur in juice processing, as required by 21 C.F.R. §§ 120.7 and 120.8;

v. Defendants perform a root cause analysis to determine sources of patulin and arsenic;

vi. Defendants have the expert validate and certify in writing to FDA that the control measures in Defendants' HACCP plan for apple and pear products are adequate to consistently control patulin;

vii. Defendants have the expert validate and certify in writing to FDA that the control measures in Defendants' HACCP plan for apple products are adequate to consistently control arsenic;

viii. The expert develops storage and traceability procedures for all food commodities, including grape juice concentrate;

ix. Defendants disclose to each customer in writing that receives any shipment as of or after the date of this Decree, all lots of juice product that has been blended into any distributed lot are within the expiration date of the final distributed lot;

x. FDA has inspected Defendants' facilities, including all records relating to the receipt, processing, manufacturing, preparation, packing, holding, and distribution of juice; and

xi. FDA has notified Defendants, in writing, that the processes and controls used for the receipt, processing, manufacturing, preparation, packing, holding, and distribution of food appear to be in compliance with all of the requirements specified in Paragraph 8 of this Decree, the Act, 21 C.F.R. Part 117 subparts A, B, and F, and 21 C.F.R. Part 120. And, if such notification is based upon one or more FDA inspections, Defendants have paid for such inspection(s) and other work at the rates specified in Paragraph 12.

9. Within ten (10) days of the entry of this Decree, Defendants shall provide to FDA an inventory of all remaining juice product, which will be stored at the facility at 130 US Grape Road, Sunnyside, WA 98944 until it is destroyed. Within two hundred seventy (270) days of the entry of this Decree, all juice product that is in the Defendants' possession at the time this Decree is signed by the parties shall be destroyed by the Defendants, at their own cost. Defendants shall provide FDA, every thirty (30) days from the date of entry of the Decree until the end of the two hundred seventy (270) day period, photographic evidence of Defendants' efforts to ship product for destruction, and a destruction report, consisting of certificates of destruction from the facility the Defendants use to dispose of the product, detailed with the quantity and lot numbers of barrels destroyed. If Defendants cannot ship any barrels of juice product for destruction within a particular thirty day period due to weather conditions or unavailability of a composter or landfill, Defendants must submit a letter to FDA detailing the reason(s) that they could not ship any product for destruction during that time period.

10. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material; to take photographs and make video recordings; to take samples of Defendants' raw

ingredients, in-process and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, preparing, processing, manufacturing, packing, holding, and/or distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

11. Defendants shall immediately provide any information or records to FDA, upon request, regarding the receipt, preparation, processing, manufacturing, packing, holding, or distribution of juice. Defendants shall maintain a copy of their HACCP plan and all records required by their HACCP plan and 21 C.F.R. Part 120 at the facility in a location where they are readily available for reference and inspection by FDA representatives. All records required to be kept by the HACCP plan and by regulation shall be retained for at least three (3) years after the date they are prepared and shall be presented immediately to FDA investigators upon request.

12. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $101.00 per hour and fraction thereof per representative for inspection work; $121.06 per hour or fraction thereof per representative for analytical or review work; $.575 per mile for travel by automobile; government rate or the equivalent for travel by

air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

13. Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who have received notice of this Decree, are permanently restrained and enjoined pursuant to the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

a. violates the Act, 21 U.S.C. § 33l(a), by introducing, or delivering for introduction, into interstate commerce, articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) or 21 U.S.C. § 342(a)(3);

b. violates the Act, 21 U.S.C. § 331(k) by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) or 21 U.S.C. § 342(a)(3), while such articles are held for sale after shipment of one or more components in interstate commerce; and/or

c. results in the failure to implement and continuously maintain the requirements of this Decree.

14. If, at any time after entry of this Decree, FDA determines, based on the results

of an inspection, sample analysis, a report or data submitted by Defendants or the expert(s), or any other information, that Defendants have failed to comply with any provision of this Decree, the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate action immediately, including, but not limited to, one or more of the following:

a. Cease receiving, processing, manufacturing, preparing, packing, holding, and/or distributing any articles of food, until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations, and that Defendants may resume operations;

b. Recall all articles of food that have been distributed and/or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

c. Submit samples of raw ingredients, in-process or finished articles of food, containers, and/or packaging materials to a qualified laboratory to determine whether they are contaminated with chemicals, toxins, microorganisms, and/or filth; and/or

d. Take any other corrective actions as FDA deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, and its implementing regulations, including, but not limited to, requiring that Defendants re-implement or re-institute any of the requirements of this Decree.

15. The provisions of Paragraph 14 shall be apart from, and in addition to, all

other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in Paragraph 12 of this Decree.

16. Upon receipt of an FDA order described in Paragraph 14, Defendants shall immediately and fully comply with the terms of the order, and shall continue to comply with such terms, until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. After a cessation of operations , and while determining whether Defendants are in compliance with this Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

17. If any Defendant fails to comply with the provisions of this Decree, the Act, and/or its implementing regulations, then Defendants shall pay to the United States of America liquidated damages in the sum of two thousand dollars ($2000.00) for each violation of this Decree, the Act, and/or its implement regulations; an additional sum of two hundred fifty dollars ($250.00) for each day that the Defendants fail to comply with this Decree, the Act, and/or its implementing regulations; and an additional sum equal to twice the retail value of each shipment of adulterated food. Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also

be the basis for payment of the liquidated damages.

18. If any Defendant violates this Decree and is found in civil or criminal contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to contempt proceedings.

19. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

20. Within ten (10) calendar days after entry of this Decree, Defendants shall:

a. provide a copy of this Decree by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates);

b. prominently post a copy of this Decree in an employee common area at

Defendants' facilities, and ensure that this Decree remains posted so long as it remains in effect; and

c. hold a meeting for their employees, at which Defendants shall describe the terms and obligations of this Decree.

Within twenty (20) calendar days after entry of this Decree, Defendants shall provide FDA with an affidavit of compliance with this Paragraph, stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

21. In the event that any Defendant becomes associated with any additional directors, officers, agents, representative, employees, attorneys, successors, assigns, or any additional persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) that are engaged in processing, manufacturing, preparing, packing, holding, and/or distributing food at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such persons. Within ten (10) calendar days after each instance that Defendant becomes associated with any individual persons, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this Paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this Paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate

Defendants' compliance with this Paragraph, Defendants shall provide such information or documentation to FDA.

22. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least ten (10) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this Paragraph within ten (10) calendar days of providing a copy of this Decree to a prospective successor or assign.

23. Defendants shall address all communications required under this Decree to the HAFW6 /Seattle District Office 22215 26th Avenue SE, Suite 210, Bothell, Washington, with a copy to orahafwest6firmresponses@fda.hhs.gov. Defendants shall prominently mark the envelope, and the email copy, as "DECREE CORRESPONDENCE," and shall reference this civil action by case name and civil action number.

24. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED this _____ day of _____, 2020.

United States District Judge

We hereby consent to the entry of the forgoing Decree:

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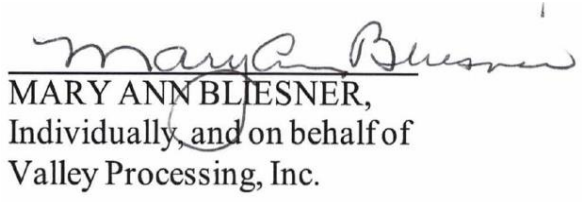
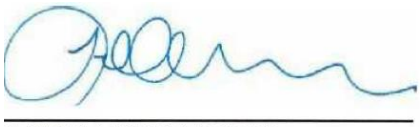
FOR DEFENDANTS:



MARY ANN BLIESNER,
Individually, and on behalf of
Valley Processing, Inc.



LILLIAN HARDY
Attorney for Defendants
Mary Ann Bliesner and Valley
Processing, Inc.